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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/512,740

03/31/2006

Neil Alexander Downie

06260 USA

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23543

7590

09/02/2010

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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

09/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/512,740	Applicant(s) DOWNIE ET AL.	
	Examiner NIHIR PATEL	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on amendment filed on 06/02/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-14, 16 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 12, 13 and 16 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 14 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL OFFICE ACTION

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on June 2nd, 2010 have been fully considered but they are not persuasive. In response to applicant's argument that the flow control valve 132 of the Lampotang reference does not maintain a correct pressure in the higher pressure section, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The flow control valve 132 of the Lampotang reference is capable of performing the intended use. A purpose of the flow control valve is to regulate the flow or pressure of a fluid indicating that a constant pressure is maintained.

The applicant further argues that the Lampotang reference does not disclose a spent gas inlet in a different (lower) pressure section from the medical gas outlet (in the higher pressure concentration). The examiner disagrees with the applicant's argument. Figure 2 of the Lampotang reference shows the spent gas inlet **14** in a different pressure section from the medical gas outlet. The inlet 14 leads to a multi gas analyzer 120 to analyze different types of gasses. The applicant further argues that the Lampotang reference does not disclose a concentration determining means measuring the concentration of at least one component of the re-circulating gas mixture. The examiner disagrees with the applicant's arguments. The multi gas analyzer 120 is capable of measuring concentrations of carbon dioxide, oxygen, nitrous oxide and volatile anesthetics see col. 13 lines 33-40.

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The applicant further argues that the Lampotang reference does not disclose two separate (first and second) feed gas flow control means of which one is response to a signal from concentration determining means and the other is responsive to a signal from a circuit volume regulating means. The examiner disagrees with the applicant's argument. Lampotang reference does disclose two separate (first and second) feed gas flow control means 200 and 202 of which one is response to a signal from concentration determining means and the other is responsive to a signal from a circuit volume regulating means (see col. 16 lines 15-37). The applicant further argues that the Lampotang reference does not disclose purification means in the medical device supply circuit for removing contaminants from the spent gas. The examiner disagrees with the applicant's argument. The carbon dioxide absorbent canister 60 of the Lampotang reference is used to absorb carbon dioxide exhaled by the patient so that the exhaled gases can be re-used. The carbon dioxide absorbent canister 60 is defined as purification means.

Response to Amendment

2. The examiner acknowledges the amendment filed on June 2nd, 2010. The amendment comprises amending the specification and amending claims 1 and 5; and cancelling claims 7, 8, 15 and 17-23.

Specification

3. The amendment filed on June 2nd, 2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "in order to maintain a constant pressure in the higher pressure section".

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Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims **1-6 and 9-14** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite subject matter “in order to maintain a constant pressure in the higher pressure section” was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims **1, 3-6 and 16** are rejected under 35 U.S.C. 102(b) as being anticipated by Lampotang et al. (US 6,131,571).

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8. **As to claim 1**, Lampotang teaches an apparatus that comprises a main gas circuit for re-circulating the medical gas mixture and comprising: a constant speed circulation pump **36** for pumping gas through the main circuit and increasing the gas pressure from a lower pressure to a higher pressure (**see fig. 2; col. 7 lines 50-55**), a pressure maintaining valve **132** downstream of the pump and dividing the main circuit into a higher pressure section and a lower pressure section (**see fig. 2; the valve has a different task in the system disclosed by the current reference but is suitable for maintaining the pressure**) in order to maintain a constant pressure in the higher pressure section (**The flow control valve 132 of the Lampotang reference is capable of performing the intended use. A purpose of the flow control valve is to regulate the flow or pressure of a fluid indicating that a constant pressure is maintained**), a medical gas outlet **14** in the higher pressure section (**see fig. 2; see col. 7 lines 20-25**), a spent gas inlet **14** (**see fig. 2; see col. 7 lines 20-25**) in the lower pressure section, a first feed gas supply inlet **200** (**see fig. 2; col. 16 lines 20-25**), a second feed gas supply inlet **202** (**see fig. 2; see col. 16 lines 20-25**) downstream of the medical gas outlet and upstream of the pressure reduction valve, concentration determining means for measuring the concentration of at least one component of the re-circulating medical gas mixture **120** (**see fig. 2; as the re-circulated gas enters the circulation loop 12 through the Y piece and the endotracheal tube 14/16**) and generating a signal **124** (**see fig. 2; col. 13 lines 35-40**) indicative of said concentration, circuit volume regulating means **212** (**see fig. 2; col. 16 lines 63-67**) for varying the volume of the main circuit at a location in the lower pressure section for maintaining a predetermined gas flow to the pump and generating a signal **226** (**see fig. 2; col. 17 lines 10-15**) indicative of said volume, and means for venting gas from the main circuit **130/150** (**see fig. 2; col. 13 lines 55-60 and col. 14 lines**

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35-40); a first feed gas supply conduit **200** (see **fig. 2; col. 16 lines 25-30**) for supply to the first feed gas supply inlet of a first feed gas of predetermined composition; first feed gas supply flow control means for controlling the flow of first feed gas through the first gas supply conduit in response to the signal from the concentration determining means to maintain constant the medical gas composition at the pump inlet (see **col. 13 lines 38-44**); a second feed gas supply conduit **202** (see **fig. 2; col. 16 lines 25-30**) for supply to the second feed gas supply inlet of a second feed gas of predetermined composition different from the first feed gas; second feed gas supply flow control means for controlling the flow of second feed gas through the second gas supply conduit in response to the signal from the circuit volume regulating means to maintain constant the recirculating medical gas composition (see **col. 21 lines 32-44**); and a medical device supply circuit **14/16** (see **fig. 2; col. 7 lines 15-30**) for connecting the medical device to the main circuit to receive a portion of the medical gas from the medical gas outlet thereof and to return spent gas to the spent gas inlet thereof and comprising: flow control means for controlling flow of the medical gas to the medical device and purification means **60** for removing contaminant(s) from the spent gas (see **fig. 2; col. 8 lines 22-30**).

9. As to **claim 3**, Lampotang teaches an apparatus wherein the pressure maintaining valve is a spill valve **182, 188, 194** (see **fig. 2; col. 15 lines 55-67 and col. 16 lines 1-10**).

10. As to **claim 4**, Lampotang teaches an apparatus wherein the circuit volume regulating means comprises expansion bellows **210** (see **col. 17 lines 1-15**).

11. As to **claim 5**, Lampotang teaches an apparatus wherein the concentration determining means comprises an analog electrical circuit for the signal thereof and the circuit volume regulating means comprises an analog electrical circuit for the signal thereof, which is of lower

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gain than of the circuit for the signal of the concentration determining means (**see col. 13 lines 24-45**), whereby the increase in flow rate of the first feed gas is quick relative to the increase in flow rate of the second feed gas (**see col. 21 lines 32-45**).

12. **As to claim 6**, Lampotang teaches an apparatus wherein the concentration determining means measures at least oxygen concentration (**see col. 13 lines 33-44**).

13. **As to claim 16**, Lampotang teaches method steps comprising recirculating the medical gas mixture in a main circuit having a higher pressure section maintained at constant pressure in series with a lower pressure section (**see fig. 2; col. 7 lines 50-55**); withdrawing a portion of the medical gas mixture from the higher pressure section and feeding said portion to the medical device (**see fig. 2; col. 13 lines 25-45**); removing contaminant(s) from the spent gas mixture from the medical device and returning the decontaminated spent gas to lower pressure section (**see col. 8 lines 22-30**); replenishing components in the medical gas mixture by addition of feed gases to maintain the recirculating medical gas composition constant; and varying the volume of the main gas circuit to maintain the gas flow therein (**see col. 17 lines 1-20**).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang et al. (US 6,131,571) in view of Siemens (EP-A-0 745 405).

17. **As to claim 2**, Lampotang substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose the feed gas supply inlets are located in the higher pressure section. Siemens discloses an apparatus that does disclose the feed gas supply inlets **10, 12 and 14** are located in the higher pressure section (**see fig. 1; col. 5 lines 19-34**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lampotang's invention by providing the feed gas supply inlets are located in the higher pressure section as taught by Siemens in order to provide the user/patient with the correct amount of gas.

18. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang et al. (US 6,131,571) in view of Dyachenko (SU-A-1 188 638).

19. **As to claim 9**, Lampotang substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose an ultrasonic xenon analyzer. Dyachenko discloses an apparatus that does disclose an ultrasonic analyzer (**see col. 1 lines 1-5**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lampotang's invention by providing an ultrasonic analyzer as taught by Dyachenko in order to control the mixture of xenon being delivered to the user/patient.

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20. Claims **12 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang et al. (US 6,131,571) in view of Vladimirovna (EP-A-0 861 672).

21. **As to claim 12**, Lampotang substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a medical device that is connected to the medical device supply circuit of an apparatus. Vladimirovna discloses an apparatus that does disclose a medical device that is connected to the medical device supply circuit of an apparatus (**see fig. 1; col. 4 lines 5-10**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lampotang's invention by providing a medical device that is connected to the medical device supply circuit of an apparatus as taught by Vladimirovna in order to minimize the leakage and to provide the correct amount of gas to the user/patient.

22. **As to claim 13**, Lampotang substantially discloses an apparatus wherein the medical device is an artificial ventilator **92 (see fig. 2; col. 8 lines 25-35)**.

Allowable Subject Matter

23. Claims **10, 11, 14 and 24** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose the means for venting gas from the main circuit comprising a gas recovery space for storing at least a portion of the vented gas or a method for the extracorporeal treatment of blood by contacting blood with a recirculating medical gas mixture in a device provided with the medical gas.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nihir Patel/

Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772